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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,259	10/31/2003	Beth P. Nguyen	PROTEO.P08CI	7361

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PROTEOTECH, INC.  
12040 115TH AVE. NE  
KIRKLAND, WA 98034

EXAMINER
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KOLKER, DANIEL E

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,259

Applicant(s)

NGUYEN ET AL.

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicant's remarks filed 11 April 2006 have been entered.

### *Election/Restrictions*

2. Applicant's election without traverse of Group I (claims 1 – 10) and heparan sulfate as the species to be examined in the reply filed on 11 April 2006 is acknowledged.
3. Claims 11 – 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 April 2006.

### *Priority*

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/007779, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '779 application does not provide support for "immobilizing... a selected sulfated glycosaminoglycan (SGAG)... on a selected medium" as recited in independent claims 1 and 10. Support for immobilizing GAGs on selected media such as glass slides can be found starting on p. 161 of provisional application 60/423185. Thus for the purposes of applying prior art, the effective filing date of all pending claims is 1 November 2002, the date that the '185 provisional application was filed.

Should applicant disagree with the examiner's factual determination above, applicant should provide evidence that a previously filed application provides support for the "immobilizing" limitation recited in claims 1 and 10. This could be accomplished, for example,

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by pointing out the page and line numbers which provide support consistent with 35 USC 112, first paragraph, in an earlier-filed application.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the word "Teflon", which is a trademark and thus describes the source of the material rather than the material itself. Use of trademarks to describe materials within a claim renders the claim indefinite. See MPEP § 2173.05(u). It is recommended that applicant amend the claim to recite the product itself rather than the trademark.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo (1997. Journal of Neurochemistry 69:2452-2465).

Castillo teaches immobilizing perlecan on microtiter wells and then adding A-beta1-40 to the wells (see p. 2454). Note that on p. 2453, first complete paragraph, Castillo teaches that "perlecan" is another name for the sulfated glycosaminoglycan heparan sulfate. Furthermore Castillo teaches that percelan increases the rate of formation of fibrils (see Figure 4 and its legend on p. 2457). Thus the reference by Castillo teaches every element of claims 1, 6, and 7. Claims 2 – 5 are drawn to specific ranges of GAG:A-beta; the broadest being 1:0.01 – 1:20, the narrowest being 1:1 on a weight-weight basis. Castillo teaches that when 1 ug of perlecan is applied to the wells, 20% (i.e. 0.2 ug) of it binds when incubated overnight, and that samples on A-beta had concentrations ranging from 0.005 – 2,000 x 10<sup>-9</sup> M in 250 ul. As the molecular

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weight of A-beta 1-40 is 4 kDa (Castillo, p. 2456, first complete paragraph), this corresponds to a range of 0.005 – 2000 ng A-beta added. Clearly Castillo's ranges included the most narrow range (1:1, that of claim 5) and thus claims 2 – 5 are anticipated by Castillo.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo (1997. Journal of Neurochemistry 69:2452-2465) in view of Cross (1989. Journal of Tissue Culture Methods 12:57-59).

The reasons why claims 1 – 7 are anticipated by Castillo are set forth above in the rejection under 35 USC 102(b). However Castillo does not teach 96-well Teflon coated slides as recited in claim 8.

Cross teaches a 96-well Teflon-coated partitioned block, which could reasonably be called a "slide", since the low friction of Teflon allows it to slide easily. Note that claim 8 sets no restrictions on the size of the so-called slide. Cross teaches that the 96-well Teflon plate is advantageous as it is compatible with both non-polar and polar solvents, and it can be sterilized and re-used. Furthermore the 96-well format is convenient for making dilutions. However Cross does not teach methods of inducing amyloid plaques as recited in claim 1.

It would have been obvious to one of ordinary skill in the art to use a 96-well Teflon slide, as taught by Cross, in the method of Castillo. The motivation to do so would be to use a format

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that is convenient to researchers, namely the 96-well format. Furthermore Cross teaches that the Teflon-partitioned slide is advantageous as it can be re-sterilized, thereby decreasing waste and cost.

8. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo in view of Cross as applied to claims 1 – 8 above, and further in view of Roach (U.S. Patent 3,494,201, issued 10 February 1970).

The reasons why claims 1 – 8 are either anticipated by (claims 1 – 7) or are rendered obvious by (claim 8) Castillo are set forth in the previous rejections. Note that Castillo teaches the method as recited in claim 10, including the ratio to be used, but neither Castillo nor Cross teaches “bubbling” as recited in claims 9 and 10.

Roach teaches pipetters which use air to displace a liquid contained within the pipetter. Roach also teaches that pressing the dispensing shaft beyond the set-point for drawing up liquid to ensure that all liquid is released (see for example column 4). The artisan of ordinary skill would have the experience to understand that when pipetting, bubbles are frequently released into the solution. This is an indication that all the solution contained within the pipet tip has left the tip and has been released into the recipient solution.

It would have been obvious to one of ordinary skill in the art to use a bubbling technique in making amyloid fibrils. The motivation to do so would be to ensure that all liquid from the pipet tip had been forced out; an air bubble would be a reliable indicator that this had been accomplished.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 6 – 9, 14 – 15, and 19-21 of copending Application No. 10/007779. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the parent application do not require that the GAGs be immobilized. However this very minor modification would be obvious to one of ordinary skill in the art as immobilizing the GAGs would allow for rapid separation of the A-beta fibrils from the GAGs after the fibrils had formed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented, although the notice of allowance has been mailed.

### ***Conclusion***

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

October 17, 2006



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER